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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John G. Babish

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/919,349

Applicant(s)

BABISH et al.

Examiner

Michele Flood

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jul 13, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO 892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO 948)
- 17) ☐ Information Disclosure Statement(s) (PTO 1449) Paper No(s)
- 18) ☐ Interview Summary (PTO-413) Paper No(s)
- 19) ☐ Notice of Informal Patent Application (PTO 152)
- 20) ☐ Other

Art Unit: 1651

## DETAILED ACTION

### *Election/Restriction*

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-25, drawn to a composition for inhibition of inducible COX-2 activity and having minimal effect on COX-1 activity, said composition comprising as a first component an effective amount of a diterpene triepoxide lactone species, and as a second component an effective amount of a sesquiterpene lactone species or derivatives thereof, classified in class 514, subclass 175, for example.
  - II. Claims 26-30 and 32-34, drawn to a method of dietary supplementation in animals comprising administering to an animal suffering symptoms of inflammation the composition comprising, as a first component an effective amount of a diterpene triepoxide lactone species and an effective amount of second component of a sesquiterpene lactone species or derivatives thereof, and continuing said administering of the composition until said symptoms are reduced, classified in class 514, subclass 914 or class 424, subclass 439, for example.
  - III. Claim 31, drawn to a method of therapeutic treatment in animals comprising administering to an animal suffering symptoms of arthritis a composition comprising, as a first component an effective amount of a diterpene triepoxide lactone species and an effective amount of second component of a sesquiterpene

Art Unit: 1651

lactone species or derivatives thereof, and continuing said administering of the composition until said symptoms are reduced, classified in class 514, subclass 825, for example.

- IV. Claims 35-39, drawn to a method of therapeutic treatment comprising applying to the skin of a human suffering symptoms of acne rosacea a lotion comprising a composition comprising as a first component an effective amount of pharmaceutical grade compound selected from a recited Markush group, and as a second component an effective amount of a compound selected from a recited Markush group, classified in class 514, subclass 859, for example.
- V. Claims 40-42, drawn to a method of therapeutic treatment comprising applying to the skin of a human suffering symptoms of psoriasis a lotion comprising a composition comprising as a first component an effective amount of pharmaceutical grade triptolide or triptonide, and as a second component an effective amount of a compound selected from a recited Markush group, classified in class 514, subclass 863, for example.

2. The inventions are distinct, each from the other because of the following reasons: Inventions and are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

Art Unit: 1651

can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, as evidenced by the claims themselves.

3. Inventions II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the four different groups are directed to four different inventions. For instance, the invention of Group II differs from the inventions of Group III-V because the invention of Group II is directed to a method of a method of dietary supplementation in animals comprising administering to an animal suffering symptoms of inflammation, whereas the invention of Group III is directed to a method of therapeutic treatment in animals comprising administering to an animal suffering symptoms of arthritis, whereas the invention of Group IV is directed to a method of therapeutic treatment comprising applying lotion to the skin of a human suffering symptoms of acne rosacea; and, whereas the invention of Group V is directed to a method of therapeutic treatment comprising applying lotion to the skin of a human suffering symptoms of psoriasis. Different methods of administering the same or essentially the same compositions by different routes of administration do not necessarily have the same functional effect, as evidenced by the claims themselves. These methods are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects.

Art Unit: 1651

4. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

5. This application also contains claims directed to numerous patentably distinct species of pharmaceutical compositions, said species containing numerous permutations of numerous ingredients. See claims 1-42.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of composition or single disclosed combination of species of composition, specifically stating which diterpene triepoxide lactone species as a first component, and specifically state which sesquiterpene lactone species as a second component, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1651

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

*Michele C. Flood*  
MCF

September 13, 2002